#### REMARKS/ARGUMENTS

Reconsideration of this application is respectfully requested.

#### I. Status of the Application

Claims 204 - 206, 208 - 212, 214 - 241, and 243 - 247 are pending, with claims 1 - 203, 207, 213, 242 and 248 - 253 having been previously canceled. Applicant cancels claims 215 - 238 without prejudice or disclaimer, and amends claims 204 - 206, 209, 210, 214, 239, 241, 244 and 245. No new matter is introduced.

#### II. Examiner Interview

Applicant thanks Examiner Morgan for holding an in-person interview with Applicant and Applicant's representative on April 30, 2008. During this interview, Applicant described the reduction to practice of his invention as provided to the general public via the web site thebody.com, and provided additional explanation and context for Declarations previously prepared and submitted with Responses of August 19, 2004 and October 31, 2007 that detail and provide evidence of the time of reduction to practice. The scope of independent claims 204, 210, 239 was also discussed. Applicant thanks Examiner for his suggestions regarding further amendments to the claims to more clearly convey the scope of Applicant's invention, which are reflected in the amendments made to the claims herein. Applicant also thanks Examiner Morgan for considering and confirming that the Declarations of August 19, 2004 and October 31, 2007 provide adequate evidence as to the time or reduction to practice of Applicant's invention as embodied in thebody.com.

#### III. Claim Rejections under 35 U.S.C. §§ 102, 103

Claims 204 - 209, 215 - 221, 224 - 229, 231 - 236, and 239 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication 2002/0002474 to Michelson et al. Claims 210 - 214, 222, 223, 237, and 238 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Michelson in view of "drkoop.com & Quintiles Launches Service to Recruit Clinical Trial Patients on the Internet," PR Newswire, June 28, 1999 ("Newswire"). Claims 230 and 240 - 244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michelson in view of U.S. Patent No. 6,171,112 to Clark ("Clark").

As claims 215 - 238 have been canceled without prejudice or disclaimer, Applicant submits that the rejections as to claims 215 - 238 are moot. Applicant amends claims 204 - 206, 209, 210, 214, 239, 241, 244 and 245 to further clarify the nature of his invention, and respectfully traverses the rejections of claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 under 35 U.S.C. §§ 102, 103. In particular, Applicant asserts that the Michelson reference must be disqualified as prior art references in the rejections under 35 U.S.C. §§ 102, 103, as Applicant's invention as claimed was conceived and reduced to practice before the effective dates of this references in the rejections of claims 245 - 247 under 35 U.S.C. §§ 102, 103, as Applicant's invention as claimed in claims 245 - 247 was conceived and reduced to practice before the effective dates of this reference.

The following reduction to practice timeline, summary of evidence in support of the timeline and support for the pending claims in the reduction to practice are provided in support Applicant's assertion.

#### Timeline of the Reduction to Practice

#### No later than May 24, 1999

Applicant makes at least the following pages accessible to members of the public as a mechanism for volunteering to be considered as participants in clinical trials, headlined as follows, and begins collecting registrations:

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http://www.thebody.com/surveys/health survey.html "Volunteer for Research!"<sup>2</sup>

http://www.thebody.com/surveys/health\_survey1.html "Volunteer for Research!/Participation Agreement"<sup>3</sup>

http://www.thebody.com/surveys/health\_survey2a.ihtml "Health Survey"4

http://www.thebody.com/surveys/health\_remove.ihtml "Removing Your Name from The Body's List of Volunteers for Research"<sup>5</sup>

#### June 28, 1999

Dr.Koop.com and Quintiles transmit a press release via Newswire ("Newswire).

#### On or about September 1,1999

Applicant begins collecting registrations of physicians interested in serving as clinical researchers of investigative drugs, at the following page.

<sup>&</sup>lt;sup>1</sup> Exhibit C, 1<sup>st</sup> Goldman Declaration

<sup>&</sup>lt;sup>2</sup> Exhibits G, I, Andrews Declaration (two separate backups of this file, dated 5/24/99); Exhibit Q, 2<sup>nd</sup> Goldman Declaration (capture with graphics by archive.org dated 10/2/99).

<sup>&</sup>lt;sup>3</sup> Exhibits H, J, Andrews Declaration (two separate backups of this file, dated 5/24/99, with headline "Volunteer for Research! Participation Agreement"); Exhibit R, 2<sup>nd</sup> Goldman Declaration (capture with graphics by archive.org dated 7/12/2000, with revised headline "Applying for Clinical Studies and Research/Participation Agreement").

<sup>&</sup>lt;sup>4</sup> Exhibit L, 2nd Marks Declaration, beginning at page 8.

<sup>&</sup>lt;sup>5</sup> Exhibit P, 2<sup>nd</sup> Goldman Declaration (capture with graphics by archive.org dated 9/12/99); Exhibits C-F, Andrews Declaration (source code from two separate backups of each of two files all dated 5/24/99, showing links from two web site pages to <a href="http://www.thebody.com/surveys/health-remove.ihtml">http://www.thebody.com/surveys/health-remove.ihtml</a>).

http://www.thebody.com/surveys/physicians.html "Research Opportunities for Physicians"

#### September 2, 1999

U.S. Postal Service (USPS) post mark date on first physician post card sent to Applicant in response to Applicant's promotion of the "Research for Physicians" page.<sup>7</sup>

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#### January 28, 2000

Michelson files Provisional Patent Application No. 60/178,634 ("the '634 Application") with the U.S. Patent & Trademark Office (USPTO).

#### April 21, 2000

Applicant files the present application with USPTO.

#### January 29, 2001

Michelson files International Application No. PCT/US1/02936.

#### August 8, 2001

Michelson files U.S. Patent Application No. 09/923,385 with the USPTO.

<sup>&</sup>lt;sup>6</sup> Exhibit M, 2<sup>nd</sup> Marks Declaration (capture with graphics by archive.org dated 1/18/2000).

<sup>&</sup>lt;sup>7</sup> Exhibit O, 2<sup>nd</sup> Marks Declaration.

#### Summary of Evidence in Support of the Timeline

As shown by the above timeline, no later than May 24, 1999, Applicant made accessible to members of the public the pages with the headlines "Volunteer for Research!," "Volunteer for Research!/Participation Agreement," "Health Survey," and "Removing Your Name from *The Body's* List of Volunteers for Research," as mechanisms enabling members of the public to self-enroll be considered as participants in clinical trials and to withdraw from participation if so desired. The pages were in all in good working order and resulted in collection of personally identifying information and medical data from actual volunteers as early as May 24, 1999, well in advance of the publication of Newswire on June 28, 1999 and the earliest U.S. patent application filing by Michelson (the '634 Application) on January 28, 2000. Applicant made accessible to physicians the page "Research Opportunities for Physicians" as a mechanism for enrolling clinical researchers on or about September 1, 1999, and received at least one physician enrollment by September 2, 1999, well in advance of the filing of Michelson's '634 Application on January 28, 2000.

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On August 19, 2004, Applicants mailed a Response to Non-Final Office Action which disqualified the Newswire reference by demonstrating by Declarations of the inventor and others familiar with the invention that the date of invention preceded the publication date of the Newswire reference (June 28, 1999). Copies of the Response of August 19, 2004, together with copies of the Declarations of James D. Marks (Exhibit 1), Bonnie Goldman (Exhibit 2), Dahlia Elsayed (Exhibit 3), and Jason K. Dewey (Exhibit 4), which were enclosed with the Response of August 19, 2004, were most recently enclosed with a Preliminary Amendment of October 31, 2007. Associated Exhibits A - D, which provide copies of certain documents described in Exhibits 1 - 4, were most recently enclosed with the Response of August 19, 2004. A second Declaration of James D. Marks (Exhibit 5), a second Declaration of Bonnie Goldman (Exhibit 6) and a Declaration of Christopher Andrews (Exhibit 7) were enclosed with the Preliminary Amendment of October 31, 2007, together with copies of associated Exhibits A - J and L - R.

operable and available to the public no later than May 24, 1999 were in fact operable and available to the public at this time. Applicant further encloses an Appendix II, which provides a summary of evidence presented in the Declarations demonstrating that the webpage described above as being operable and available to the public no later than September 1, 1999 was operable and available to the public at this time.

As supported by the Declarations, Applicant submit that each of the elements of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 was reduced to practice on or before **September 1, 1999**, and that each of the elements of pending claims 245 - 247 was reduced to practice on or before **May 24, 1999** as further described below.

#### Support for Claims in Reduction to Practice

The rejections of claims 204 - 206, 208 - 212, 214 - 241, and 243 - 247 are in each case based on the Examiner's application of Michelson either as an anticipatory reference under 35 U.S.C. § 102(e), or as a reference which in combination with one of Newswire or Clark under 35 U.S.C. § 103(a) is asserted by the Examiner as making the claimed subject matter obvious. Michelson discloses an on-line forum for the exchange of clinical trial information among trial study sponsors, study investigators and potential study subjects (see, e.g., abstract of Michelson).

As the application filing date of April 21, 2000 for the present application predates Michelson's application filing date of August 8, 2001, Michelson qualifies as a prior art reference only by claiming priority under 35 U.S.C. § 120 from International Application No. PCT/US1/02936, which was filed on January 29, 2001, and further under 35 U.S.C. § 119(e) to Provisional Patent Application No. 60/178,634 ("the '634 Application"), which was filed on January 28, 2000.

With respect to the Timeline and Evidence in Support of the Timeline as presented above, Applicant has demonstrated that certain web pages supporting Applicant's system for recruiting potential candidates for clinical trials were operable and available to the public prior to the effective date for Michelson (January 28, 2000). In Attachment III, Applicant shows how each \(\text{W:\21351\000g956-us0\01531438.DOC}\)

of the elements of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 finds support in the Applicant's Declarations. Attachment III clearly demonstrates that the invention as claimed was reduced to practice <u>prior</u> to Michelson's effective date of **January 28, 2000**. In addition, Applicant demonstrates that the invention as claimed in claims 245 - 247 was reduced to practice prior to Newswire's effective date of **June 28, 1999**.

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Accordingly, Applicant respectfully submits that because Michelson (and, for claims 245 - 247, Newswire) have an effective date that falls <u>after</u> Applicant's reduction to practice of the claimed invention, these references fail to qualify as prior references with regard to each of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247, and must therefore be removed. Applicant submits that pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 therefore are allowable for at least this reason, and respectfully requests that the rejections of pending claims 204 - 206, 208 - 212, 214, 239 - 241, and 243 - 247 under 35 U.S.C. §§ 102, 103 be withdrawn.

#### Conclusion

Therefore, in view of the above amendments and remarks, it is respectfully requested that a Notice of Allowance as to all pending claims be issued in this case.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Dated: June 9, 2008 Respectfully submitted,

Thomas J. Bean

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Attorneys/Agents For Applicant

Attachments

Application No. 09/556,945 Amendment mailed June 9, 2008 In Response to Office Action of February 7, 2008

#### ATTACHMENT I: WEBPAGES OPERABLE AT THEBODY.COM AS OF MAY 29, 1999

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#### 1. "Volunteer for Research" Page

Title: "Volunteer for Research"

Location: http://www.thebody.com/surveys/health\_survey.html

Illustrations: Andrews Declaration, Exhibit G; 2<sup>nd</sup> Goldman Declaration, Exhibit Q

#### Evidence of reduction to practice as of May 24, 1999:

"I found [the file] labeled as follows on [website backup tapes] A01 [and] ... on A02: <a href="http://www.thebody.com/surveys/health\_survey.html">http://www.thebody.com/surveys/health\_survey.html</a>[.] ... I confirmed that the file system metadata states the date on which the [file was] created and, assuming the system clock was accurate on the machine that copied the original data to the tapes, confirmed that [the file was] created on May 24, 1999.

Andrews Declaration, paragraphs 9, 10 and 11.

"As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at <a href="www.thebody.com">www.thebody.com</a>: The page headlined, "Volunteer for Research" at <a href="http://www.thebody.com/surveys/health\_survey.html">http://www.thebody.com/surveys/health\_survey.html</a> (substantially in the form attached as Exhibit G of the Declaration of Christopher Andrews)...."  $2^{nd}$  Goldman Declaration, paragraph 6.

"The [page] posted at TheBody.com headlined, "Volunteer for Research" ... in addition to being substantially in the form of [Exhibit] G ... in the Declaration of Christopher Andrews, [was] moreover as of May 24, 1999 substantially in the form later captured at archive.org (showing .jpg graphics) on October 2, 1999 ... at the following [URL]:

http://web.archive.org/web/19991002035408/http://www.thebody.com/surveys/health\_survey.html.... and [is] attached ... in current hardcopy form as [Exhibit] Q."

#### 2. "Volunteer for Research!/Participation Agreement" Page

Title: "Volunteer for Research!/Participation Agreement"

Location: http://www.thebody.com/surveys/health\_survey1.html

Illustrations: Andrews Declaration, Exhibit H; 2<sup>nd</sup> Goldman Declaration, Exhibit R

#### Evidence of reduction to practice as of May 24, 1999:

"I found [the file] labeled as follows on [website backup tapes] A01 [and] ... on A02: <a href="http://www.thebody.com/surveys/health\_survey1.html[.]">http://www.thebody.com/surveys/health\_survey1.html[.]</a> ... I confirmed that the file system metadata states the date on which the [file was] created and, assuming the system clock was accurate on the machine that copied the original data to the tapes, confirmed that [the file was] created on May 24, 1999.

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Andrews Declaration, paragraphs 9, 10 and 11.

"As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at <a href="www.thebody.com">www.thebody.com</a>: The page headlined, "Volunteer for Research!/Participation Agreement" at <a href="http://www.thebody.com/surveys/health-survey1.html">http://www.thebody.com/surveys/health-survey1.html</a> (substantially in the form attached as Exhibit H of the Declaration of Christopher Andrews)...."  $2^{nd}$  Goldman Declaration, paragraph 6.

"The [page] posted at TheBody.com headlined, "Volunteer for Research!/Participation Agreement" ... in addition to being substantially in the form of [Exhibit] H ... in the Declaration of Christopher Andrews, [was] moreover as of May 24, 1999 substantially in the form later captured at archive.org (showing .jpg graphics) on October 2, 1999 ... at the following [URL]:

http://web.archive.org/web/20000712022808/http://www.thebody.com/surveys/health\_survey1. html.... and [is] attached ... in current hardcopy form as [Exhibit] R."  $2^{nd}$  Goldman Declaration, paragraph 8.

#### 3. "Health Survey" Page

Title: "Health Survey"

Location: <a href="http://www.thebody.com/surveys/health\_survey2a.ihtml">http://www.thebody.com/surveys/health\_survey2a.ihtml</a> Illustration: 2<sup>nd</sup> Marks Declaration, Exhibit L, beginning on page 8

#### Evidence of reduction to practice as of May 24, 1999:

"As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at <a href="www.thebody.com">www.thebody.com</a>: ... [T]he page headlined, "Health Survey" at <a href="http://www.thebody.com/surveys/health\_survey2a.ihtml">http://www.thebody.com/surveys/health\_survey2a.ihtml</a> (substantially in the form attached as Exhibit L of the Second Declaration by James D. Marks....  $2^{nd}$  Goldman Declaration, paragraph 6.

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"As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at TheBody.com:... [T]he page headlined, "Health Survey" as <a href="http://www.thebody.com/surveys/health\_survey2a.ihtml">http://www.thebody.com/surveys/health\_survey2a.ihtml</a> (substantially in the form attached as Exhibit L to this Declaration)...." 2nd Marks Declaration, paragraph 6.

"Upon information and belief, BHRC kept in its insurance policy files screen snapshots of the [page] headlined ... "Health Survey", [a copy] of which [is] attached to this Declaration as Exhibit L. Upon information and belief, all of the original hardcopies were snapped on August 11, 1999, and submitted by BHRC's attorneys at Paul, Weiss, Rifkind, Wharton and Garrison to BHRC's insurance agent, Marsh & McLennan with BHRC's application for Errors and Omissions Insurance on August 16, 1999."

2nd Marks Declaration, paragraph 9.

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#### 4. Removal Page

Title: "Removing Your Name from The Body's List of Volunteers for Research"

Location: http://www.thebody.com/surveys/health\_remove.ihtml

Illustration: 2<sup>nd</sup> Goldman Declaration, Exhibit P

#### Evidence of reduction to practice as of May 24, 1999:

"As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at <a href="www.thebody.com">www.thebody.com</a>: ... [T]he page headlined, "Removing Your Name from The Body's List of Volunteers for Research" at <a href="http://www.thebody.com/surveys/health-remove.ihtml">http://www.thebody.com/surveys/health-remove.ihtml</a>. Upon information and belief, the Removal Page was substantially in the form later captured on September 12, 1999 at archive.org (an entity independent of BHRC) which may be viewed currently at <a href="http://web.archive.org/web/19990912024121/http://www.thebody.com/surveys/health-remove.ihtml">http://web.archive.org/web/19990912024121/http://www.thebody.com/surveys/health-remove.ihtml</a>, a current hardcopy of which is attached as Exhibit P. <a href="mailto:2<sup>nd</sup> Goldman Declaration">2<sup>nd</sup> Goldman Declaration</a>, paragraph 6.

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"As of May 24, 1999 at the latest, the Health Survey Questionnaire accessible to members of the public included at least the following web site [page] posted at TheBody.com:... [T]he page headlined, "Removing Your Name from *The Body's* List of Volunteers for Research" at <a href="http://www.thebody.com/surveys/health-remove.ihtml">http://www.thebody.com/surveys/health-remove.ihtml</a>, substantially in the form attached as Exhibit P to the Second Declaration of Bonnie Goldman...."  $2^{nd}$  Marks Declaration, paragraph 6.

"I confirmed that health\_survey.html [file creation date confirmed through metadata to be May 24, 1999] as it appears on each backup tape (A01, A02) contains the text, "Please remove my name as a volunteer," into which is coded a hypertext link to the following page: <a href="http://www.thebody.com/surveys/health\_remove.ihtml">http://www.thebody.com/surveys/health\_remove.ihtml</a>. I also confirmed that health\_survey1.html [file creation date confirmed through metadata to be May 24, 1999] as it appears on each backup tape (A01, A02) contains the text, "This release shall be effective for a perpetual duration, but you may subsequently request that The Body no longer provide information to clinical researchers," and into the underlined portion is coded a hypertext link to the following page: <a href="http://www.thebody.com/surveys/health\_remove.ihtml">http://www.thebody.com/surveys/health\_remove.ihtml</a>."

Andrews Declaration, paragraph 12.

#### ATTACHMENT II: WEBPAGES OPERABLE AT THEBODY.COM AS OF SEPTEMBER 1, 1999

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#### 5. Physician Registration Page

Title: "Research Opportunities for Physicians"

Location: http://www.thebody.com/surveys/physicians.html

Illustrations: 2<sup>nd</sup> Marks Declaration, Exhibits M - O

#### Evidence of reduction to practice as of September 1, 1999:

I further conceived of, supervised and controlled the design and implementation of a web site page on www.thebody.com headlined, "Research Opportunities for Physicians," (the Physician Registration Page) at which BHRC invited registration of physicians interested in serving as clinical researchers of investigative drugs. The page was substantially in the form captured on January 18, 2000 at archive.org (an entity independent of BHRC), ...and which may be viewed currently at

http://web.archive.org/web/20000118011618/http://thebody.com/surveys/physicians.html 2<sup>th Marks Declaration, paragraph 10, 11.</sup>

[A] form letter and enclosures used in a September 1, 1999 mailing from BHRC [] invited physician registration. The form letter encloses a copy of the upper portion of the Physician Registration Page as an illustration, and a response post card which was provided as an alternative to registering online. [Post] cards sent in the promotional mailing, filled out and returned by physicians, [show] U.S.P.S. cancellation stamps of September 2 and September 3, 1999. Upon information and belief, the Physician Registration Page was available to the public at <a href="http://www.thebody.com/surveys/physicians.html">http://www.thebody.com/surveys/physicians.html</a> on or about September 1, 1999. 2nd Marks Declaration, paragraph 10.

### ATTACHMENT III SUPPORT FOR CLAIMS PROVIDED BY DECLARATIONS

INDEPENDENT CLAIMS

#### Claim Elements

204. A method of acquiring information from individuals who want to volunteer for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

#### **Declaration Support**

- An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5).
- the body.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3)
- Multiple responses to a Health Survey Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

#### Claim Elements

#### providing a health survey form for display on one of the plurality of end-user computer terminals, the one end-user computer terminal being accessible to at least one of the individuals, the health survey form soliciting from the individual contact information by which the one individual may be contacted, and at least one of the individual's personal medical and information from which the individual may be evaluated as a potential candidate for any of the plurality of clinical trials, whereby the individual agrees to volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials:

#### **Declaration Support**

- A Health Survey Questionnaire was installed on the server hosting thebody.com no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).
- The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 6).

receiving first information supplied by the individual via the one end-user computer terminal, the first information including the individual's contact information, personally-identifying information of the individual and the at least one of the individual's personal and medical information;

• As of May 25, 1999, responses to the Health Survey Questionnaire had been accepted at thebody.com from for at least two respondents (Declaration of James D. Marks, pg. 3)

storing the at least one of the individual's contact information and the at least one of the individual's personal and medical information in a database, thereby registering the individual for ongoing consideration as a potential candidate for participating as a research subject in any of the plurality of clinical trials;

- Health Survey Questionnaire responses were first retrieved from thebody.com and stored no later then May 24, 1999 (Declaration of Dahlia Elsayed, pg. 3)
- The stored Health Survey Questionnaire responses contained contact information, other personal information and medical information (Exhibit C).

Claim Elements	Declaration Support
wherein registration of the individual precedes registration of one or more of the plurality of clinical trials.	<ul> <li>Health Survey Questionnaire responses were stored beginning no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 4)</li> </ul>
	• A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).

#### **Declaration Support**

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210. A method by which an individual may register as a volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of a plurality of clinical trials, and by which the individual may subsequently opt out of the registration, by means of a server operated by the recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

Claim Elements

- An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5).
- the body.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3)
- Thebody.com included a web page entitled "Removing Your Name from *The Body's* List of Volunteers for Research" (the Removal page), which was accessible from the web page entitled "Volunteer for Research," and available no later than **May 24**, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, pgs. 3, 4).
- Multiple responses to a Health Survey Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

Claim Elements

# providing a health survey form on one of the plurality of end-user computer terminals soliciting from the individual contact information by which the individual may be contacted and at least one of the individual's personal and medical information from which the individual may be evaluated as a potential candidate for any of the plurality of clinical trials, whereby the individual agrees to volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of the plurality of clinical trials;

receiving first information supplied by the individual via the one end-user computer terminal, the first information including the individual's contact information, personally-identifying information of the individual and the at least one of the individual's personal and medical information:

storing the individual's contact information, the personally-identifying information of the individual and the at least one of the individual's personal and medical information in a database, thereby registering the individual for ongoing consideration as a potential candidate for participating as a research subject in any of the plurality of clinical trials,

#### **Declaration Support**

- A Health Survey Questionnaire was installed on the server hosting thebody.com no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 2)
- The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 6).
- As of May 25, 1999, responses to the Health Survey Questionnaire had been accepted at thebody.com from for at least two respondents (Declaration of James D. Marks, pg. 3)
- Health Survey Questionnaire responses were first retrieved from thebody.com and stored no later then May 24, 1999 (Declaration of Dahlia Elsayed, pg. 3)
- The stored Health Survey Questionnaire responses contained contact information, other personal information and medical information (Exhibit C).

Claim Elements	Declaration Support
wherein registration of the individual precedes registration of one or more of the plurality of clinical trials;	<ul> <li>Health Survey Questionnaire responses were stored beginning no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 4)</li> </ul>
	• A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).
receiving second information supplied by the individual via the one end-user computer terminal or another one of the plurality of end-user computer terminals, the second information including the personally-identifying information of the individual and information indicating a request by the individual to withdraw the registration; and	• Prior to May 24, 1999, staff of thebody.com verified that the Removal page was operable to receive a withdrawal request from a registered individual, together with personally-identifying information of the registered individual, and transmit this information to the server (Second Declaration of Bonnie Goldman, pg 4).
storing the personally-identifying information of the individual and information in the database indicating the individual's request to withdraw the registration.	• Prior to May 24, 1999, staff of thebody.com were instructed to periodically download and store withdrawal requests, and to delete stored Health Survey Questionnaire for registered individuals associated with the withdrawal requests (Second Declaration of Bonnie Goldman, pg 4).

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#### Claim Elements

239. A method of on-line recruitment of individuals who want to volunteer with a recruitment service provider for ongoing consideration as potential candidates for participating as research subjects in any of a plurality of clinical trials, by means of a server operated by the recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

- An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5).
- the body.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3)
- Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

Claim Elements

the

individuals.

of the plurality of clinical trials;

the

#### **Declaration Support** providing a participation agreement for A web page entitled "Volunteer for display on one of the plurality of end-user Research/Participation Agreement" computer terminals that is accessible to one providing access to **Participation** a participation Agreement for display on an end-user agreement soliciting consent from the terminal was available at thebody.com and individual to be considered on an ongoing archived as early as May 24, 1999 (Second basis for selection as a potential candidate Declaration of Bonnie Goldman, pgs. 3, 4, for participating as a research subject in any Declaration of Christopher Andrews, page 3). The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Questionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J. pgs. 1 - 3.5receiving a signal from the one end-user The Participation Agreement included computer terminal indicating the individual's an "I accept" button which was selectable consent to the participation agreement; by clicking on the button at the user terminal to provide electronic consent (Exhibit J, pg. 5) Non-receipt of the electronic consent at the server precluded acceptance of a Health Survey Questionnaire response by the recruitment service provider

Declaration of James D. Marks, pg. 4)

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(Second

#### Claim Elements

## providing a health survey form, for display on the one end-user computer terminal, and soliciting contact information; and at least one of personal and medical information for the individual from which the individual may be evaluated as a potential candidate for any of the plurality of clinical trials;

#### **Declaration Support**

- A Health Survey Questionnaire was installed on the server hosting thebody.com no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).
- The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 6).

receiving information transmitted by the individual via the one of the plurality of enduser computer terminals, the information containing the contact information and at least one of the relevant personal and medical information; and

- With receipt of the electronic consent at the server, the Health Survey Questionnaire response is accepted by the recruitment service provider (Second Declaration of James D. Marks, pg. 4)
- As of May 25, 1999, responses to the Health Survey Questionnaire had been accepted at the body.com from for at least two respondents (Declaration of James D. Marks, pg. 3)

storing the individual's contact information and the at least one of the individual's personal and medical information in a database, thereby registering the individual for consideration as a candidate for participating as a research subject in any of the plurality of clinical trials,

- Health Survey Questionnaire responses were first retrieved from thebody.com and stored no later then May 24, 1999 (Declaration of Dahlia Elsayed, pg. 3)
- The stored Health Survey Questionnaire responses contained contact information, other personal information and medical information (Exhibit C).

Claim Elements	Declaration Support
wherein registration of the individual precedes registration of one or more of the plurality of clinical trials.	<ul> <li>Health Survey Questionnaire responses were stored beginning no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 4)</li> <li>A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).</li> </ul>

#### **Declaration Support**

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# 245.: A method by which an individual may register as a volunteer to be considered on an ongoing basis for selection as a potential candidate for participating as a research subject in any of a plurality of clinical trials, and by which the individual may subsequently opt out of the registration, by means of a server operated by a recruitment service provider, the server being configured to communicate with a plurality of end-user computer terminals via a network, the method comprising the steps of:

Claim Elements

- An announcement provided in a web page entitled "Volunteer for Research," was created and archived no later than May 24, 1999 (Declaration of Christopher Andrews, page 3). In an announcement made on May 26, 1999, thebody.com announced that it will act as a recruitment service provider by compiling a database including information about volunteers volunteering for possible participation in medical trials (Declaration of James D. Marks, pgs. 4, 5).
- thebody.com operated on leased server space hosted by Interport Communications Corp. (Declaration of Bonnie Goldman, pg. 3).
- Thebody.com included a web page entitled "Removing Your Name from *The Body's* List of Volunteers for Research" (the Removal page), which was accessible from the web page entitled "Volunteer for Research," and available no later than **May 24, 1999** (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, pgs. 3, 4).
- Multiple responses to a Health Survey Questionnaire for recruitment posted by the body.com, most likely received at and transmitted by a plurality of end-user terminals, were received at thebody.com as of May 25, 1999 (Declaration of Jason K. Dewey, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).

computer terminals accessible

consent to the participation agreement;

individual.

clinical trials;

Claim Elements

to

**Declaration Support** providing a participation agreement for A web page entitled "Volunteer for display on one of the plurality of end-user Research/Participation Agreement" the providing access to **Participation** a the participation agreement Agreement for display on an end-user soliciting consent from the individual to be terminal was available at thebody.com and considered on an ongoing basis for selection archived as early as May 24, 1999 (Second as a potential candidate for participating as a Declaration of Bonnie Goldman, pgs. 3, 4, research subject in any of the plurality of Declaration of Christopher Andrews, page 3). The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Questionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J, pgs. 1 - 3, 5receiving a signal from the one end-user The Participation Agreement included computer terminal indicating the individual's an "I accept" button which was selectable by clicking on the button at the user terminal to provide electronic consent (Exhibit J, pg. 5) Non-receipt of the electronic consent at the server precluded acceptance of a Health Survey Ouestionnaire response by the

recruitment service provider

Declaration of James D. Marks, pg. 4)

(Second

#### **Declaration Support**

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providing a health survey form for display on the one end-user computer terminal, the health survey form soliciting contact information by which the individual may be contacted, and at least one of the individual's personal and medical information from which the individual may be evaluated as a potential candidate for any of the plurality of clinical trials;

Claim Elements

- A Health Survey Questionnaire was installed on the server hosting thebody.com no later than May 24, 1999 (Declaration of Bonnie Goldman, pg. 2). The Health Survey Questionnaire was made accessible via the "Volunteer for Research" web page, each of which was available no later than May 24, 1999 (Declaration of Christopher Andrews, page 3 and Exhibit I, Second Declaration of Bonnie Goldman, page 2).
- The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 6).

receiving first information supplied by the individual via the one end-user computer terminal, the information containing the individual's contact information, personally-identifying information of the individual and the at least one of the individual's personal and medical information;

- With receipt of the electronic consent at the server, the Health Survey Questionnaire response is accepted by the recruitment service provider (Second Declaration of James D. Marks, pg. 4)
- As of May 25, 1999, responses to the Health Survey Questionnaire had been accepted at thebody.com from for at least two respondents (Declaration of James D. Marks, pg. 3)

receiving second information supplied by the individual via the one end-user computer terminal or another one of the plurality of end-user computer terminals, the second information including the personally-identifying information of the individual and information indicating a request by the individual to withdraw the registration; and

Prior to May 24, 1999, staff of thebody.com verified that the Removal page was operable to receive a withdrawal request from a registered individual, together with personally-identifying information of the registered individual, and transmit this information to the server (Second Declaration of Bonnie Goldman, pg 4).

Claim Elements	Declaration Support
the server storing the personally-identifying information of the individual and information indicating the individual's request to withdraw the registration in the database.	, , ,

### ATTACHMENT III SUPPORT FOR CLAIMS PROVIDED BY DECLARATIONS DEPENDENT CLAIMS

Defent	DENT CLAIMS
Claim Elements	Declaration Support
Claim 205. The method of claim 204, wherein the individual's agreement signifies an agreement by the individual to release the contact information to a representative of any one or more of the plurality of clinical trials.	• A web page entitled "Volunteer for Research/Participation Agreement" providing access to a Participation Agreement for display on an end-user terminal was available at thebody.com and archived as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, page 3).
	• The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Questionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J, pgs. 1 - 3, 5).
	• The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6).
Claim 206. The method of claim 204, wherein the health survey form solicits identification of one or more medical conditions of the individual relevant to one or more of the plurality of clinical trials.	• The Health Survey Questionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6).
Claim 208. The method of claim 204, wherein the network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network:	• No later than May 24, 1999, thebody.com server posted the Health Survey Questionnaire for access via the Internet (Declaration of Bonnie Goldman, pg. 2).

Claim Elements	Declaration Support
Claim 209. The method of claim 204, further comprising the step of: providing registration information for display on a second end-user computer terminal, said registration information soliciting information for registering a clinical researcher to participate in one or more of the plurality of clinical trials.	• On or about September 1, 1999, a web page entitled "Research Opportunities for Physicians" was available at thebody.com and invited registration of physicians interested in serving as clinical researchers (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 3, 4).
Claim 211. The method of claim 210, wherein the personally-identifying information includes a name of the individual in combination with a second personal identifier of the individual.	• Prior to May 24, 1999, staff of thebody.com verified that the Removal page was operable to receive a withdrawal request from a registered individual including the individual's name and birth date, and transmit this information to the server (Second Declaration of Bonnie Goldman, pg 4)
Claim 212. The method of claim 210, wherein the second personal identifier is a date of birth of the individual	• The Health Survey Questionnaire solicited contact information and other personal information such as birthdate (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pg. 6.

Claim Elements

wherein the first information transmitted

information to a representative of any one

Claim 240. The method of claim 239,

wherein the participation agreement is a

wherein the health survey form solicits the

identification of one or more medical

conditions of the individual relevant to one

or more of the plurality of clinical trials

click-wrap agreement.

Claim 241.

or more of the plurality of clinical trials.

#### **Declaration Support** Claim 214. The method of claim 210, A web page entitled "Volunteer for Research/Participation Agreement" by the individual signifies an agreement a Participation providing access to by the individual to release the contact Agreement for display on an end-user terminal was available at thebody.com and archived as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4, Declaration of Christopher Andrews, page 3). The Participation Agreement indicates that an individual participant is consenting to allow the recruitment service provider to provide information from the Health Survey Ouestionnaire to clinical researchers for the purpose of being matched with clinical studies and considered as a participant for an appropriate clinical trial (Exhibit J, pgs. 1 - 3, 5). The Health Survey Ouestionnaire solicited contact information, other personal information and medical information (Second Declaration of James D. Marks, pg. 2 and Exhibit L, pgs. 1 - 6). A web page providing access to a Participation Agreement for display on an end-user terminal available was thebody.com as early as May 24, 1999 (Second Declaration of Bonnie Goldman, pgs. 3, 4) The Participation Agreement provides a click-wrap "I accept" button signifying consent to the agreement (Exhibit J, pg. 5). The Health Survey Questionnaire solicited contact information, other personal information and medical information

(Second Declaration of James D. Marks, pg.

2 and Exhibit L, pgs. 1 - 6).

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The method of claim 239,

Claim Elements	Declaration Support
Claim 243. The method of claim 239, wherein the network comprises one or more of the Internet, the World Wide Web, an intranet, a local area network, a wide area network and a wireless communications network.	• No later than May 24, 1999, thebody.com server posted the Health Survey Questionnaire for access via the Internet (Declaration of Bonnie Goldman, pg. 2).
Claim 244. The method of claim 239, further comprising the step of: providing registration information for display on a second end-user computer terminal, said registration information soliciting information for registering a clinical researcher to participate in one or more of the plurality of clinical trials.	• A solicitation of physician investigators conducting clinical trials began no later than September 1, 1999 (Second Declaration of James D. Marks, pg 4). This solicitation was facilitated by a web page entitled "Research Opportunities for Physicians," accessible to the general public via thebody.com (Second Declaration of James D. Marks, pg 3).
Claim 246. The method of claim 245, wherein the personally-identifying information includes a name of the individual in combination with a second personal identifier of the individual.	• The Removal page was operable to receive the name of a registered individual, and to transmit this information operation of a "submit" button on the Removal Page (Second Declaration of Bonnie Goldman, pg 3).
Claim 247. The method of claim 246, wherein the second personal identifier is a date of birth of the individual.	• The Removal page was operable to receive identifying information (a "birthdate") of a registered individual, and to transmit this information operation of a "submit" button on the Removal Page (Second Declaration of Bonnie Goldman, pg 3).